

Vice President

John Venardos Worldwide Regulatory & Government Affairs

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NOV 22 Herbalite International of America INC

1800 Century Park East. Century City CA 90067

T 310.410.9600 F 310.557.3916

e-mail: johnv@herbalife.com

October 25, 2005

Dr. Robert J. Moore Branch Chief, Compliance & Enforcement Branch Office of Nutrition Products, Labeling & Dietary Supplements FOOD & DRUG ADMISTRATION (HFS-800) 5100 Paint Brush Parkway College Park, Maryland 20740

Ref: Herbal Tea Concentrate (N392-00, N393-00, N547-00, N546-00)

Dear Dr. Moore:

Pursuant to 21CFR§101.93, please be advised Herbalife International of America, Inc. has introduced Herbal Tea Concentrate. Labeling bears the following structure/function claim:

> Herbal Tea Concentrate This delicious low-calorie tea mix blends green tea and orange pekoe with cardamom seed, lemon peel, hibiscus and natural sources of caffeine for an uplifting taste treat.* Caffeine is known for its natural thermogenic (metabolism-boosting) benefits and green tea for its antioxidant properties.* Studies have shown that regular consumption of moderate amounts of caffeine can support weight control.* Enjoy refreshing Herbal Concentrate as part of your weight-loss program or whenever you want a boost.*

Herbal Tea Concentrate is labeled and promoted with statements provided for in Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

The product label prominently bears the required ruled DSHEA disclaimer statement: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

Please be advised that we have substantiation on file that these claims are truthful and not misleading.

If you have any questions, please do not hesitate to ask.

Sincerely.

2605-7708 Aims

225cc





Herbal Tea Concentrate

For Increased Energy and Metabolism*

Natural Flavor NET WT 3.53 oz / 100 g

Herbal Tea Concentrate This delicious low-calorie tea mix blends green tea and orange pekoe with cardamom seed, lenion peel, hibiscus and natural sources of caffeine for an uplifting taste treat.* Caffeine is known for its natural thermogenic (metabolism-boosting) benefits and. green tea for its antioxidant properties.* Studies have shown that regular consumption of green tea can support good health and regular consumption of moderate amounts of caffeine can support weight control*. Enjoy refreshing Herbal Concentrate as part of your weight-loss program or whenever you want a boost."

DIRECTIONS: Mix & teaspaon (more or less as desired) of Herbai Concentrate with 6 to 8 fl. ox, hot or cold water and enjoy. HISTRUCCHES: Mezcle X cucharadite (use más a meios sagún su gusto) de Harbal Concentrata con 6 a 8 ez. fi. de agua callente o tria y distrútelo.

We offer a 38-day money-back guarantee to assure your complete satisfaction. This exclusively formulated product is only available through Please note this product contains catteine.

NOTICE: Anyone, especially children and pregnant or tactating women, should contail a physician before considering any weight-central program Advierta que este producto contiene cafeina.

ANISO: Cipalquier persona, especialmonte alias; mujeres embarazadas y sodruzas deben consultar a su médico anles de emperar chaliquier programa de centrol de peza. Contiena ingrediantes de Soya.

Supplement

Serving Size: ¼ teaspoon (1.7 g) Servings Per Container: 60

Camillia sinensis Tea Blend 475 mg (Orange Pekoe and Green Tea) Heroal Blend (Cardamom Seed Extract, Malva sylvestris Extract and Hibiscus Flower Powder

(from Natural Caffeine Powder, Orange Pekoe and Green Tea)

* Percent Daily Values are based on a 2,000 calorie diet † Daily Value not established.

OTHER INGREDIENTS: Maltodextrin, Fructose Powder, Natural Lemon Flavor, Citric Acid. 🥳 Acesulfame Potassium, Safflower Oil and Silicon Dioxide. Contains Soybean Ingredients

MADE IN U.S.A.

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FINAL ART#: 1

JOB#. 53396

FILE: LFX0188US-47-02 225cc DESC: herbal tea lemon

DOC SIZE: 7.18" x 2.5" PRINT SCALE: 135.5%

ARTIST: Yoojin Lee

DATE: 10/24/05 - 3:20 PM

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For Increased Energy and Metabolism*

Natural Flavor

NET WT 3.53 oz / 100 g

Herbal Tea Concentrate This delicious tow-calorie tea mix blends green tea and grange pekoe with cardamom seed, lemon peel, hibiscus and natural sources of caffeine for an uplifting taste treat." Caffeine is known for its natural thermogenic (metabolism-boosting) benefits and green tea for its antioxidant properties.* Studies have shown that regular consumption of green tea can support good health and regular consumption of moderate amounts of catterine can sunnort weight control.* Enjoy retreshing Herbal Concentrate as part of your weight loss program or whenever you want a boost.*

BIRECTIONS: Mix X teaspoon (more or less as desired) of Herbal Concentrate with 5 to 6 ft. oz. hot or cold water and enjoy. INSTRUCCIONES: Mezcle Y cucharadita juxe más o menos según su auste) de Herbal Concentrate con 8 a 8 ez. fl. de agua callente o

We offer a 18-day money-back guarantee to assure your complete satisfaction, this exclusively formulated product is only available tarough Herbalife independent Distributors

Please note this product contains calfinise MOTICE: Anyone, especially children and pregnant or factaling women, should consult a physician before considering any weight control program Advierta que este producto contigne caleiga.

WISO, Cualquier dersona, especialmente niños, mujeres embarazadas y Andrizas deben consultar o su médico antes de empezar cualquier programa de control do poss. Cantiene ingrendantes de Soya.

HERBALITE INTERNATIONAL OF AMERICA, INC., Les Angeles, CA 90080-0210, U.S.A.

Supplement Facts

Serving Size: ½ teaspoon (1.7 g) Servings Per Container: 50

Total Carbohydrate Camillia sinensis Tea Blend 475 mg (Orange Pekoe and Green Tea)

Herbal Blend (Cardamom Seed Extract.

Malva sylvestris Extract and Hibiscus Flower Powder) (from Natural Caffeine Powder, Orange Pekce and Green Tea)

* Percent Daily Values are based on a 2,000 calone diet † Daily Value not established.

OTHER INGREDIENTS: Maltodextrin, Fructose Powder, Natural Lemon Flavor, Citric Acid, 🥳 Acesulfame Potessium, Safflower Oil and Silicon Dioxide.

Contains Soybean Ingredients

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FINAL ART# 1

IOB#: 53396

FILE: LFX0188US-47-02 225cc DESC: herbal tea lemon

DOC SIZE: 7.18" x 2.5" PRINT SCALE: 135.5%

ARTIST. Yoojin Lee DATE: 10/24/05 - 3:20 PM

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For Increased Energy and Metabolism*

peach

Natural Flavor Dictary Supplement NET WT 3.53 oz / 100 g

Herbal Tea Concentrate This delicious low-calorie tea mix blends green tea and crange pekee with cardamom seed, lemon peel, hibiscus and natural sources of caffeine for an uplifting taste treat." Caffeine is known for its natural thermogenic (metabolism-boosting) benefits and green tea for its antioxidant properties.* Studies have shown that regular consumption of green tea can support good health and regular consumption of moderate amounts of caffeine can support weight control*: Enjoy refreshing Herbal Concentrate as part of your weight-loss program or whenever you want a boost,*

DIRECTIONS: Mix /s teaspoon (more or less as desired) of Herbal Concentrate with 6 to 8 ft. oz. hot or cold water and enjoy. INSTRUCCIONES: Mezcle /s cucharadita (use más o menos según su gustal de florbel Congentrate con 6 a 8 oz. 0. de ague caliente o fria y distrateio.

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We offer a 30-day mean-back guarantée to assure your complete satisfaction This exclusively formulated product is only available through Herhalite Independent Distributors.

Please pote this product contains catteins MOTICE: Anyone, especially children and pregnant or factating nomen, should coased a physician before considering any weight-control program.

Advierta que este producto contiene caferna. AVISO. Cualquier persona, especialmente niños, mujeras embai azadas y nodrizas debea consultar a su mádica antes de empezar cualquier programa

HERBALIFE INTERNATIONAL OF AMERICA, INC., Los Augens, CA 90080-0710, U.S.A.

Supplement Facts

Serving Size: ½ teaspoon (1.7 g) Servings Per Container: 60

Total Carbohydrate Camilla sinensis Tea Blend 550 mg

(Orange Pekoe, Green Tes and Black Tea) Herbal Blend (Cardamom Seed Extract,

Malva sylvestris Extract and Hibiscus Flower Powder) Caffeine

(from Natural Caffeine Powder, Orange Pekoe, Green Tea and Black Tea)

** Percent Daily Values are based on a 2,000 calorie diet. † Darly Value not established

OTHER INGREDIENTS: Maltodextrin, Fructose Powder, Natural Peach Flavor and Citric Acid.

MADE IN U.S.A.

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	FILE: LFX3035US-47-33 225cc		
DESC: Herbal Tea-Peach			
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Herbal Tea Concentrate

For Increased Energy and Metabolism* peach

Natural Flavor Dietary Supplement

NET WT 3.53 oz / 100 g

Herbal Tea Concentrate This delicious low-calorie tea mix blends green tea and orange pekoe with cardamom seed, lemon peel, hibiscus and natural sources of caffeine for an upliffing taste treat." Caffeine is known for its natural thermogenic (metabolism-hoosting) benefits and green tes for its antioxidant properties.* Studies have shown that regular consumption of green tea can support and health and regular consumption of moderate amounts of caffeine can support weight control*. Enjoy refreshing Herbal Concentrate as part of your weight-loss program or whenever you want a boost."

DIRECTIONS: Mix X teaspoon (more or less as desired) of Herba Concentrate with 6 to 8 ft. ez. but or cold water and enjoy. INSTRUCCIONES: Mezcle X cucharadita fuse más o menos según su gusto) de Herbal Concentrate con 6 a 8 oz. fi. de agua caliente o fria v distrutelo.

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We offer a 30-day money-back guarantee to assure your complete satisfaction. This exclusively formulated product is only available through Herbalife Independent Distributors Please sole this product contains cattein

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AVISD: Cualquier persona, especialmente niños, mujeres embarazadas y nodrezas deben consultar a su médico antes de emperar cualquier programi

HERBALIFE INTERNATIONAL OF AMERICA, INC., Los Angeles, CA 90080-0210, U.S.A.

Supplement

Serving Size: ¼ teaspoon (1.7 g) Servings Per Container: 80

Amount Per Serving % Daily Value* Total Carbohydrate

Camillia sidensis Tea Blend 550 mg (Orange Pekoe, Green Tea and Black Tea)

Herbal Blend

(Cardamom Seed Extract, Malva sylvestris Extract and Hibiscus Flower Powder)

Caffeine. 85 mg (from Natural Caffeine Powder, Orange Pekoe,

Green Tea and Black Tea) * Percent Daily Values are based on a 2,000 calorie diet.

† Daily Value not established. STHER INGREDIENTS: Maltedextrin.

Fructose Powder, Natural Peach Flavor and Citric Acid.

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FINAL ART#: 1

08#: 53397 FILE: LFX3035US-47-33 225cc DESC: Herbal Tea-Peach

DOC SIZE: 7.18" x 2.5" PRINT SCALE: 135.5%

ARTIST: Yoojin Lee DATE: 10/24/05 - 3:15 PM

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For Increased Energy and Metabolism*

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Natural Flavor
Dietary Supplement
NET WT 3.53 oz / 100 g

Herbal Tea Concentrate This delicious low-calorie tea mix blends green tea and orange pekoe with cardamom seed, hibiscus and natural sources of catteline for an uplifting taste treat.* Caffeine is known for its natural thermogenic (metabolism-boosting) benefits and green tea tor its antioxidant properties.* Studies have shown that regular consumption of green tea can support good health and regular consumption of moderate amounts of caffeine can support weight control. Enjoy refreshing Herbal Concentrate as part of your weight-loss program or whenever you want a boost.*

DIRECTIONS: Mix % teaspiess (more or less as desired) of Nerbal Concentrate with 8 to 8 ft. sz. hat ar cold water and onjoy. INSTRUCTIONES: Morcle % cucharadith (use mix a menos según su gusto) de Herbai Concentrate con 6 a 8 oz. ff. de agua callente o

tria y extretien. We offer a 36-day money-back guarantee to assure your complete satisfaction. This exclusively formulated product is only available through Harbaths Independent Distributors

Phase note this product contains caffeing.

**ROTIES: Anyone, expecially children and pregnant or lactating women, should consult a physician before considering any weight control program. Advierta que este producto contiene cafeina. AVISO: Crastquier persona, especialmente miños, majeros embarazadas y

nodrizas deben consultar a su medico antes de empezar cualquier programa

HERBALTE INTERNATIONAL OF AMERICA, INC., Los Angeles, CA 93000 0210, U.S.A.

Supplement Facts

Serving Size: X teaspoon (1.7 g) Servings Per Container-Sii

Amount Per Serving % Daily Value*

fotal Carbonydrate Gamillia sinensis Tea Blend 475 mg

(Orange Pekoe and Green Tea)

Herbal Blend (Cardamom Seed Extract,

Malva syivestris Extract and Hibiscus Flower Powder)

85 mg Caffeine (from Natural Caffeine Powder, Orange Pekoe and Green Tea)

** Percent Daily Values are based on a 2,000 calone diet † Daily Value not established

GTHER (HEREDIENTS: Maltodextrin, Natural Raspherry Flavor, Fructose Powder, Citric Acid, Acesultame Potassium, Safflower Oil and Silicon Dioxide

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7.18" x 2.5" Pharmachem





FINAL ART#: 1

108#: 53398

FILE: LFX0189US-47-02_225cc DESC: herbal tea raspberry

DOC SIZE: 7.18" x 2.5" PRINT SCALE: 135.5%

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Herbal Tea Concentrate

For Increased Energy and Metabolism* raspberry Natural Flavor Dietary Supplement

NET WT 3.53 oz / 100 g

Herbal Tea Concentrate, This delicious low-calorie tea mix blends green tea and orange pekoe with cardamom seed, hibiscus and natural sources of caffeine for an uplifting taste treat.* Caffeine is known for its natural thermogenic (metabolism-boosting) benefits and green tea for its antioxidant properties.* Studies have shown that regular consumption of green tea can support good health and regular consumption of moderate amounts of caffeine can support weight control.". Enjoy refreshing Herbal Concentrate as part of your weight loss program or whenever you want a boost.*

DIMECTIONS: Mix X tempoon (more or less as desired) of Herbal Concentrate with 5 to 8 ft. oz. hot or cold water and enjoy. INSTRUCCIONES: Mozolo % cucharadite (use más a menos según su

inaxinoctronics inector in contravaries user mas a mesos segon to gestor) dis firstal Concentrate on 6 a 8 c. fl. de ague caliente o fris y distrirtets.

We offer 3.0-yar inner-hack guarantee lo assure your competet salvisaction. This exclusively famulated product is only available through the ability independent Destribulers. Please note this product contains caffeine.

MOTICE: Anyone, especially children and pregnant or lactating women, should consult a physician before considering any weight-control program ovisort a prosecute acoustic consumer any mergin control program.
AVISTE Cualquies persona, especialmente niños, queres embarazadas y
indiciais deligio consultar a su médico antes de emparar casteirer programa

HERBALIEC INTERNATIONAL OF AMERICA, INC., Los Angeles, CA 90080-0210, U.S.A.

Supplement Fact:

Serving Size: K teaspoon (1.7 g) Servings Per Container: 60

Total Carbohydrate

Camillia siliensis Tea Blend 475 mg (Orange Pekoe and Green Tea)

Herbal Blend

(Cardamom Seed Extract.) Malva sylvestris Extract and Hibiscus Flower Powder)

Caffeine (from Natural Calleine Powder, Orange Pekoe and Green Tea)

** Percent Daily. Values are based on a 2,000 calorie diet

† Daily Value not established

OTHER INGREDIENTS: Mailtodextrin, Natural Raspberry Flavor, Fructose Powder, Citric Acid, Acesulfame Potassium, Saftlower Oil and Silicon Dioxide

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FINAL ART#: 1

OB#: 53398 FILE: LFX0189US-47-02_225cc

DESC: herbal tea raspberry DOC SIZE: 7.18" x 2.5"

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ARTIST: Yoojin Lee DATE: 10/24/05 - 3:17 PM

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For Increased Energy and Metabolism*

original
Dietaly Supplement

NET WT 3.53 oz / 100 g

Herbal Tea Concentrate This delicious low-calorie tea mits blends green tea and orange pekoe with cardamom seed, temon peet, hibbscas and natural sources of caffeine for an uplifiting taste treat.* Caffeine is known for its natural themogenic (metabolism-boosting) benefits and green tea for its antioxidant properties. Studies have shown that regular consumption of green tea can support good health and regular consumption of moderate amounts of catfeine can support weight control.* Enjoy refreshing Herbal Concentrate as part of your weight-loss, program or whenever you want a boost.*

OMECTIONS: Mix X teaspape (more or less as desired) of Herbal Ceacontrate with 6 to 8 ff. oz. hot or cold water and anjay. MIXTRUCCHMIS: Molect & concharabita (use más o menos según su gnato) de Herbal Ceneditato con 6 a 8 ez. ff. de agua callente o Triay distribute.

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MRTICEs Anyone, especially children and pregnant or Jactating winner, should consult a physician before considering any weight children pregram. Advivors que lests produce controller catelina.

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AVISO: Cualquier persona, especialmente minos, mujeres embarazadas y opdrizas deben consultar o an mágico autos do ampozar evalueiro programa de control de paso. Comilieno lagratilantos de Soya.

HERBALIFE INTERMATIONAL OF AMERICA, INC., Los Angeles, CA 90080-0210, U.S.A.

Supplement Facts

Serving Size: ½ teaspoon (1.7 g) Servings Per Container: 60

Amount Por Serving **Clasity Value***

Calories 1 g 13%

Camillia sineusis Fee Bland 550 mg 1 f/drange Pekae, Green Tee and Black Tea)

Herbal Blend 245 mg †

(Cardamom Seed Extract,

Malva sylvestris Extract and Hibiscus Flower Powder)

Caffeine 85 mg †

(from Natural Caffeine Powder, Orange Pekoe, Green Tea and Black Téa)

** Percent Daily Values are based on a 2,000 calorie diel † Daily Value not established.

OTHER INGREDIENTS: Fructose Powder, Maltodektrin and Lemon Peel Extract. Contains Soybean Ingredients.

ns Soybean Ingredients.

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7.18" x 2.5" Pharmachem





FINAL ART#: 1

JOB#: 53395

FILE: LFX1195US-47-34_225cc

DESC: Herbal tea

DOC SIZE: 7.18" x 2.5"

PRINT SCALE: 135.5%

ARTIST: Yogjin Lee

DATE: 10/24/05 - 3:22 PM

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Herbal Tea Concentrate

For Increased Energy and Metabolism*

original

NET WT 3.53 oz / 100 g

Herbal Tea Concentrate This delicious low-calorie tea mix blends green tea and orange pekoe with cardamom seed, lemon peel, hibiscus and natural sources of caffeine for an upliffing taste treat. Caffeine is known for its natural thermogenic (metabolism-boosting) benefits and green tea for its antioxidant properties.* Studies have shown that regular consumption of green tea can support good health and regular consumption of moderate amount of caffeine can support weight control.* Enjoy refreshing Herbal Concentrate as part of your weight-loss program or whenever you want a boost.*

DIRECTIONS: Mix X teaspoon (more or less as desired) of Herbal Concentrate with 6 to 8 ft. oz. hot or cold water and enjoy. INSTRUCCIONES: Mescre X cocharadita (use más o menos según su gusto) de Aeribal Concentrate con 6 a 8 oz. 11, de agua caliente o iria y disfrátela.

satisfaction. This exclusively formulated product is only available through Herbatile independent Distributors

Please note this product contains caffeing NOTICE: Anyone, especially children, and pregnant or lactating women, should consult a physician before considering any weight control program rerla que este producto contione cafeina.

AVISO: Cualquior persona, especialmente piños, muieres embarazadas y nodrizas deben consultar a su médico antes de ambezas gualquier progras de control de peso. Contiene ingresiónies de Sóys.

HERBALIFE HITEMBATHONAL DF ÁMERICA, IHC., LOS ÁNGOLOS, CA 90080-0210, U.S.A.

Supplement Fact:

Serving Size: % teaspoon (1.7 g) Servings Per Container: 68

Amount Per Serving %Dally Value* Total Carbobydrate

Camillia sinensis Tea Blend 550 mg (Orange Pekoe, Green Tea and Black Tea)

Herbal Blend (Cardamoni Seed Extract,

Malva sylvestris Extract and Hibiscus Flower Powder

(from Natural Caffeine Powder, Orange Pekoe, Green Tea and Black Tea)

** Percent Darly Values are based on a 2,000 calorie diet * Opily Value not established.

OTHER INGREDIENTS: Fructose Powder, Maltodextrin and Lemon Peel Extract. Centains Soybean Ingredients.

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JOB#: 53395 FILE: LFX1195US-47-34_225cc DESC: Herbal tea

DOC SIZE: 7.18" x 2.5" PRINT SCALE: 135.5%

ARTIST: Yoojin Lee DATE: 10/24/05 - 3:22 PM









